

the fact, and shall state, that the replacement or supplemental deposit is of a biological material which is identical to that originally deposited;

(3) Includes a verified showing that the patent owner acted diligently—

(i) In the case of a replacement deposit, in making the deposit after receiving notice that samples could no longer be furnished from an earlier deposit or

(ii) In the case of a supplemental deposit, in making the deposit after receiving notice that the earlier deposit and become contaminated or had lost its compability to function as described in the specification;

(4) Includes a verified statement that the term of the replacement or supplemental deposit expires no earlier than the term of the deposit being replaced or supplemented; and

(5) Otherwise establishes compliance with these regulations, except that if the person making one or more of the required statements or showing is an attorney or agent registered to practice before the Office, that statement or showing need not be verified.

(d) A depositor's failure to replace a deposit, or in the case of a patent, to diligently replace a deposit and promptly thereafter request a certificate of correction which meets the terms of paragraphs (b) and (c) of this section, after being notified that the depository possessing the deposit cannot furnish samples thereof, shall cause the application or patent involved to be treated in any Office proceeding as if no deposit were made.

(e) In the event a deposit is replaced according to these regulations, the Office will apply a rebuttable presumption of identity between the original and the replacement deposit where a patent making reference to the deposit is relied upon during any Office proceeding.

(f) A replacement or supplement deposit made during the pendency of an application for patent may be made for any reason.

(g) In no case is a replacement or supplemental deposit of a biological material necessary where the biological material, in accordance with § 1.802(b), need not be deposited.

(h) No replacement deposit of a biological material is necessary where a depository can furnish samples thereof but the depository for national security, health or environmental safety reasons is unable to provide samples to requesters outside of the jurisdiction where the depository is located.

(i) The Office will not recognize in any Office proceeding a replacement deposit of a biological material made by a patent owner where the depository could furnish samples of the deposit being replaced.

§ 1.806 Term of deposit.

A deposit made before or during pendency of an application for patent shall be made for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposit was received by the depository. In any case, samples must be stored under agreements that would make them available beyond the enforceable life of the patent for which the deposit was made.

§ 1.807 Viability of deposit.

(a) A deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. No evidence is necessarily required regarding the ability of the deposited material to perform any function described in the patent application.

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

- (1) The name and address of the depository;
- (2) The name and address of the depositor;
- (3) The date of deposit;
- (4) The identity of the deposit and the accession number given by the depository;
- (5) The date of the viability test;

(6) The procedures used to obtain a sample if the test is not done by the depository; and

(7) A statement that the deposit is capable of reproduction.

(c) If a viability test indicates that the deposit is not viable upon receipt, or the examiner cannot, for scientific or other valid reasons, accept the statement of viability received from the applicant, the examiner shall proceed as if no deposit has been made. The examiner will accept the conclusion set forth in a viability statement issued by a depository recognized under § 1.803(a).

§ 1.808 Furnishing of samples.

(a) A deposit must be made under conditions that assure that:

(1) Access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Commissioner to be entitled thereto under § 1.14 and 35 U.S.C. 122, and

(2) Subject to paragraph (b) of this section, all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent.

(b) The depositor may contract with the depository to require that samples of a deposited biological material shall be furnished only if a request for a sample, during the term of the patent:

(1) Is in writing or other tangible form and dated;

(2) Contains the name and address of the requesting party and the accession number of the deposit; and

(3) Is communicated in writing by the depository to the depositor along with the date on which the sample was furnished and the name and address of the party to whom the sample was furnished.

(c) Upon request made to the Office, the Office will certify whether a deposit has been stated to have been made under conditions which make it available to the public as of the issue date of the patent grant provided the request contains:

(1) The name and address of the depository;

(2) The accession number given to the deposit;

(3) The patent number and issue date of the patent referring to the deposit; and

(4) The name and address of the requesting party.

§ 1.809 Examination procedures.

(a) The examiner shall determine pursuant to § 1.104 in each application for patent, application for reissue patent or reexamination proceeding if a deposit is needed, and if needed, if a deposit actually made is acceptable for patent purposes. If a deposit is needed and has not been made or replaced or supplemented in accordance with these regulations, the examiner, where appropriate, shall reject the affected claims under the appropriate provision of 35 U.S.C. 112, explaining why a deposit is needed and/or why a deposit actually made cannot be accepted.

(b) The applicant for patent or patent owner shall respond to a rejection under paragraph (a) of this section by—

(1) In the case of an applicant for patent, making an acceptable original or replacement or supplemental deposit or assuring the Office in writing that an acceptable deposit will be made on or before the date of payment of the issue fee, or, in the case of a patent owner, requesting a certificate of correction of the patent which meets the terms of paragraphs (b) and (c) of § 1.805, or

(2) Arguing why a deposit is not needed under the circumstances of the application or patent considered and/or why a deposit actually made should be accepted. Other replies to the examiner's action shall be considered non-responsive. The rejection will be repeated until either paragraph (b)(1) of this section is satisfied or the examiner is convinced that a deposit is not needed.

(c) If an application for patent is otherwise in condition for allowance except for a needed deposit and the Office has received a written assurance that an acceptable deposit will be made on or before payment of the issue fee, the Office will mail to the applicant a Notice of Allowance and Issue Fee Due together with a requirement that the needed deposit be made within three months. The period for satisfying this requirement is extendable under § 1.136. Failure to make the needed deposit in